11 510(k) Summary

11.1 SPONSOR'S NAME & ADDRESS

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

JUN 22 2010

11.2 OFFICIAL CORRESPONDENT

Melissa C. Schultz
Project Manager, Regulatory Affairs
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11.3 SUBMISSION DATE

April 21, 2010

11.4 TRADE NAME

SOUNDSTAR 3D Ultrasound Catheter

11.5 COMMON NAME

Electrophysiology Mapping/Ultrasound Catheter

11.6 CLASSIFICATION NAME/PRODUCT CODE

Intravascular Ultrasound Catheter/OBJ

11.7 CLASSIFICATION

Class II

11.8 PREDICATE DEVICE

SOUNDSTAR 3D Ultrasound Catheter, model M-5723-12 (K092064) cleared on August 7, 2009.

11.9 DESCRIPTION OF DEVICE

The Biosense Webster SOUNDSTAR 3D Ultrasound Catheter is a 90 cm 10F IntraCardiac Echo (ICE) Catheter with an acoustic array identical to the Biosense Webster SOUNDSTAR 3D Ultrasound Catheter, model M-5723-12, Ultrasound Catheter. The catheter has a location sensor (providing location information to CARTO® EP Navigation Systems with ultrasound capability) and an ultrasound transducer (acquiring real time ultrasound images) embedded in the tip.

The SOUNDSTAR 3D Ultrasound Catheter has a bifurcated 'tail' originating from its handle. One leg terminates in the SOUNDSTAR tab connector, which connects via a Swiftlink cable to an ultrasound system. The other leg terminates in the CARTO® Hypertronic connector, which connects via a Patient Interface Unit (PIU) extension cable to the CARTO® Navigation System.

The SOUNDSTAR 3D Ultrasound Catheter, when connected to a CARTO® EP Navigation System with ultrasound capability, and the GE Vivid-i or Vivid-q Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO® electromagnetic acquired maps.

11.10 INDICATIONS FOR USE

The Biosense Webster SOUNDSTAR 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® EP Navigation Systems, the SOUNDSTAR 3D Catheter provides location information.

11.11 DESCRIPTION OF MODIFICATION

The modified SOUNDSTAR 3D Ultrasound Catheter is physically ***identical*** to the predicate device in terms of design, manufacturing methods, materials and performance. There are absolutely no changes to the device whatsoever. The only modification is to the labeling for the device to allow compatibility with multiple CARTO® EP Navigation Systems with ultrasound capability.

11.12 SUMMARY OF NONCLINICAL TESTS

All testing previously submitted for the predicate SOUNDSTAR 3D Ultrasound Catheter, model number M-5723-12, still applies to the modified device as there were no changes to the design, materials,

manufacturing methods or performance of the device. In addition, various functionality testing was performed on the SOUNDSTAR Catheter, model number M-5723-05, with GE Vivid-i/q Ultrasound System and CARTO® 3 System functionality. Testing verified that the three components, when connected simultaneously, functioned appropriately as designed. This additional functionality testing which was performed on the SOUNDSTAR Catheter, model number M-5723-05, demonstrates equivalence to the modified device (model number M-5723-12), as SOUNDSTAR Catheter, model number M-5723-05 is nearly identical to the predicate SOUNDSTAR Catheter, model number M-5723-12, with the exception that the identification codes in the catheter connectors are different. The predicate device, the SOUNDSTAR Catheter, model number M-5723-12, is physically ***identical*** to the modified device (model number M-5723-12), which is the subject of this submission. The only modification to model number M-5723-12 is to the labeling of the device to allow compatibility with multiple CARTO® EP Navigation Systems with ultrasound capability. Testing for compatibility with the CARTO® 3 EP Navigation Systems is referenced in the Compatibility Summary Report found in **Appendix 3**.

11.13 SUBSTANTIAL EQUIVALENCE

The modified SOUNDSTAR 3D Ultrasound Catheter is identical to the previously cleared SOUNDSTAR 3D Ultrasound Catheter in that the devices:

- have the same intended use,
- use the same operating principle,
- use the same fundamental scientific technology,
- incorporate the same design,
- incorporate the same materials and construction,
- have the same shelf life, and
- are packaged using the same materials and processes.

In summary, the SOUNDSTAR 3D Ultrasound Catheter described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biosense Webster, Inc
c/o Ms. Melissa Schultz
Project Manager, Regulatory Affairs
3333 Diamond Canyon Rd
Diamond Bar, CA 91765

JUN 22 2010

Re: K101138
Trade/Device Name: Soundstar 3D Ultrasound Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: OBJ
Dated: May 25, 2010
Received: May 26, 2010

Dear Ms. Schultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Villalobos

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) No (if known): K101138

Device Name: SOUNDSTAR 3D Ultrasound Catheter

Indications for Use:

The Biosense Webster SOUNDSTAR 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® EP Navigation Systems, the SOUNDSTAR 3D Catheter provides location information.

Prescription Use (Part 21 CFR 801 Subpart D) √ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101138